DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850

95184

FEB 15 2005

*Via Federal Express*

**WARNING LETTER**

Jerald L. Tennant, M.D.
Senergy Medical Group
Biofeedback Clinic
5601 North MacArthur Blvd., Ste 200
Irving, Texas 75038

Dear Dr. Tennant:

The purpose of this Warning Letter is to inform you of objectionable conditions found during a Food and Drug Administration (FDA) inspection conducted at your clinical site. This letter also acknowledges your undated Fascimile letter received by FDA's Dallas District Office on November 30, 2004, addressed to Michael Chappell, and requests that you implement prompt corrective actions. Mr. Marc Dickens, an investigator from the FDA's Dallas District Office conducted the inspection from October 5 through October 10, 2004. The purpose of the inspection was to determine if your activities and procedures as a sponsor and clinical investigator for the [redacted] study complied with applicable FDA regulations. The [redacted] is a device as that term is defined under Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The FDA conducted the inspection under a program designed to ensure that data and information contained in requests for Investigational Device Exemptions (IDE), Premarket Approval Applications (PMA), or Premarket Notification [510(k)] submissions are scientifically valid and accurate. The program also ensures that human subjects are protected from undue hazard or risk during scientific investigations.

Our review of the inspection report submitted by the Dallas District Office revealed serious violations of Title 21, Code of Federal Regulations (21 CFR), Part 812 – Investigational Device Exemptions, and Part 50-Protection of Human Subjects, and Section 520(g) of the Act. At the close of the inspection, Mr. Dickens presented a Form FDA 483 "Inspectional Observations" to you for review and discussed the listed deviations. The deviations noted on the Form FDA 483 and our subsequent inspection report review are discussed below:

***Failure to obtain a signed investigator agreement (21 CFR 812.43(c)).***

A signed agreement that includes a statement of the investigator's commitment to conduct an investigation in accordance with the agreement, investigational plan, applicable FDA regulations, conditions of approval imposed by the reviewing IRB, and conditions of approval imposed by the FDA was not obtained from each participating investigator for the [redacted]

***Failure to obtain adequate informed consent (21 CFR 812.100 and 21 CFR 50.20, 50.25, and 50.27(a)).***

Pursuant to 21 CFR 812.100, an investigator is responsible for ensuring that informed consent is obtained in accordance with 21 CFR Part 50. In accordance with 21 CFR 50.20, "no investigator may involve a human being as a subject in research covered by these regulations unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative." The informed consent shall be documented by the use of a written consent form approved by the IRB and signed and dated by the subject or the subject's legally authorized representative at the time of consent. (21 CFR 50.27(a)). Examples of your failure to comply with the informed consent requirements include but are not limited to the following:

- The informed consent form used did not have an IRB approval signature or date printed on the document. Approval of the informed consent form was not specifically documented in any of the IRB correspondence documents.

- Subjects [redacted] did not sign the informed consent form. Subjects [redacted] signed the questionnaire instead of signing the informed consent form and subject [redacted] and [redacted] had no informed consent form in their files.

- The informed consent document used to obtain consent from subjects enrolled in the study lacked required elements and contained exculpatory language that released or appeared to release the investigator and those involved with the study from liability for negligence.

- A description of benefits to the subject was not documented. Specifically, the informed consent states "The conditions chosen to be studied are conditions that have a natural course of worsening with time and for which traditional medical therapy is only partially effective." This paragraph does not document what "conditions" are being studied, nor does it document what about these "conditions" might be improved through these treatments.

- In the informed consent, the term "Minimal Risk" is used. In addition to this, the informed consent does not address any significant risks that the subject should be made aware of. The informed consent states that "[redacted] has been used since recorded medical history of approximately 2000 years." The consent form then states "literature does not suggest any significant risk to this type of therapy except that it can aggravate the normal functioning of implanted electrical devices such as pacemakers." This appears to be a statement that should also be included in the protocol as an exclusion criteria.

- The informed consent form lacked an explanation of whom to contact for answers to questions about the research, research subject's rights, and research related injuries.

- Appropriate alternate procedures that might be advantageous to subjects were not described in the informed consent.

- Under the reasons that a subject can be terminated from the study without their approval, you did not identify non-compliance as a reason for termination.

- The informed consent states that the subject may be part of the control group and not receive any therapy whatsoever; however, there was no "control" group in this study.

The informed consent does not state the approximate number of subjects involved in the study. The informed consent states that there will be ten subjects in each group. However, the informed consent does not state how many groups there are. The informed consent states that the subject selects their study group (the kind of treatment they will receive); however, during the closeout discussion you stated that the subjects did not select their treatment group. Rather the subjects were assigned to treatment groups in rotation. For example, one subject would be enrolled in [redacted]; one in [redacted], one in [redacted], one in [redacted] and then the rotation would start over. Although, this does not appear to have been the case because the [redacted] and [redacted] devices were used almost exclusively rather than the above stated rotation.

***Failure to maintain accurate, complete, and current records (21 CFR 812.140(a)).***

Pursuant to 21 CFR 812.140(a), clinical investigators must maintain accurate, complete, and current records relating to the investigator's participation in an investigation. You failed to satisfy these requirements in that some patient records were left blank or did not contain the requested information and did not have documentation necessary to support data appearing in case report forms.

***Failure to establish written procedures for monitoring the investigation (21 CFR 812.25); Failure to ensure proper monitoring of the investigational study (21 CFR 812.40).***

Pursuant to 21 CFR 812.25, a sponsor is responsible for providing written procedures for monitoring the investigation. Pursuant to 21 CFR 812.40, a sponsor must ensure proper monitoring of the investigation. You failed to designate a monitor or establish procedures or guidelines for monitoring this study.

***Failure to adhere to the investigational plan (21 CFR 812.100 and 21 CFR 812.110(b)).***

Pursuant to 21 CFR 812.100 and 812.110(b), clinical investigators are required to ensure that investigations are conducted according to the signed agreement, the investigational plan, and applicable FDA regulations, as well as any conditions of approval imposed by the IRB or FDA. The investigational plan for the [redacted] Study lacked the following:

> The investigational plan required that treatments be documented on the case report forms for each subject and that questionnaires documenting the patient's visual perceptions be completed. Documentation of the treatments were not completed on the case report forms nor were questionnaires completed.

***Failure to submit complete, accurate, and timely reports of unanticipated adverse device effects (21 CFR 812.150(a)(1)).***

FDA regulations require an investigator to submit a report of any unanticipated adverse device effect occurring during an investigation as soon as possible, but in no event later than 10 working days after the investigator first learns of the effect. Adverse events for subjects [redacted] and [redacted] were not reported to the IRB as adverse events.

The above described deviations are not intended to be an all-inclusive list of deficiencies that may exist in this clinical study. It is your responsibility as a sponsor and clinical investigator to ensure that you adhere to applicable FDA regulations.

Within fifteen (15) working days after receiving this letter please provide written documentation of the additional specific steps you have taken or will take to correct these violations and prevent the recurrence of similar violations in current and future studies.

In addition to the above, we are concerned that your two sons ([redacted] and [redacted]), serve as members of the IRB that reviewed and approved your study. Since you are the sponsor and clinical investigator for this study, your family members should not participate as voting members in an IRB meeting that is reviewing your study.

We are also concerned that your post card advertisements and pamphlet advertisements both utilize the Food and Drug Administration in the advertisement. The pamphlet states "An FDA study" and the post card states "Free FDA study". This is not FDA's study and you must remove the statements claiming that this is an FDA study. These are false and misleading statements.

While we acknowledge that you stated in your letter that you are committed to coming into compliance and that you have suspended the study until you are in compliance, your letter lacks specific corrective action regarding informed consent. Any submitted corrective action plan must include projected completion dates for each action to be accomplished. We look forward to your promised response. Failure to respond to this letter and take further appropriate corrective action could result in FDA taking regulatory action without further notice to you. Please send your response to: Food and Drug Administration, Center for Devices and Radiological Health, Office of Compliance, Division of Bioresearch Monitoring, Program Enforcement Branch (HFZ-312), 2094 Gaither Road, Rockville, Maryland 20850, Attention: Viola Sellman, Chief, Program Enforcement Branch.

We are also sending a copy of this letter to FDA's Dallas District Office, 4040 North Central Expressway, Suite 300, Dallas, Texas 75204. We request that you also send a copy of your response to that office. If you have any questions, please contact Ms. Sellman at (240) 276-0125, or by email at vxs@cdrh.fda.gov.

Sincerely yours,

Timothy A. Ulatowski
Director
Office of Compliance
Center for Devices and
Radiological Health